



STATE OF TENNESSEE
BUREAU OF TENNCARE
DEPARTMENT OF FINANCE AND ADMINISTRATION
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

The State of Tennessee, TennCare Bureau PHARMACY PARTICIPATION AGREEMENT For Ambulatory and Long Term Care Pharmacy Providers

Section 10.1 of the TennCare PHARMACY PARTICIPATION AGREEMENT states:

Amendment. This Agreement may be amended by TennCare. TennCare may amend this Agreement (a) to comply with applicable court orders, consent decrees, laws or regulations or (b) to affect any necessary policy changes by giving thirty (30) days written notice of an amendment to Pharmacy.

The TennCare Pharmacy Participation Agreement is amended by the replacement of the sections or subparts within specific sections with the language below. The pharmacy provider does not need to sign and return any documents to TennCare.

THIS AGREEMENT effective _____ is between the State of Tennessee, TennCare Bureau, Department of Finance and Administration (hereinafter referred to as TennCare) and _____ (hereafter referred to as Pharmacy).

WHEREAS, the State of Tennessee, TennCare Bureau is responsible for the financial, clinical and managerial aspects of the TennCare pharmacy program for TennCare/Medicare enrollees and behavioral health pharmacy services and the total pharmacy benefit for all TennCare enrollees after July 1, 2003, and;

WHEREAS, the Pharmacy is desirous to participate in contractual prescription filling activities under this TennCare program, and;

WHEREAS, the State of Tennessee, TennCare Bureau provides drug benefit programs to TennCare enrollees through arrangements with regional and statewide pharmacy networks; and,

WHEREAS, participating pharmacies are members of the TennCare Bureau's network, contractually bound to meet TennCare standards, including but not limited to, emergency services, compliance with the *Grier* Revised Consent Decree, maintenance and review of patient profiles, patient consultation and medication information and utilization review; and,

WHEREAS, the Pharmacy and TennCare desire to promote high standards of pharmaceutical care on a cost effective basis through drug utilization review activities.

SECTION 1 DEFINITIONS

Drug Formulary: Prior to July 1, 2003, reimbursement for pharmacy services is limited to only those drugs covered by the TennCare Pharmacy Program for the all eligible TennCare/Medicare enrollees and all TennCare behavioral health pharmacy services for eligible TennCare enrollees. This TennCare program may utilize a negative drug formulary list. This is a list of drugs that are **NOT** covered by TennCare. The TennCare Bureau may develop this negative drug formulary list and make any changes subsequent to its implementation on or after July 1, 2000. Any changes to this negative drug formulary list will not take place until thirty (30) days after all affected providers are notified. A maintenance drug list and any over-the-counter (OTC) drugs covered by this program will be listed in a separate formulary. This negative drug formulary list, the maintenance drug list and the OTC list will be distributed to pharmacies and posted on the TennCare website (www.tennessee.gov/tenncare). Coverage and reimbursement for legend, maintenance and OTC drugs by the TennCare program is contingent upon a prescription written by a licensed prescriber. OTC drugs that are required to be floor stock items in a long term care facility will not be covered for nursing home residents.

After July 1, 2003, following notice from TennCare, reimbursement for pharmacy services will be limited to the TennCare preferred drug list (PDL). This PDL will apply to all prescriptions for all TennCare enrollees. The PDL will be distributed to pharmacy providers and posted on the TennCare website (www.tennessee.gov/tenncare).

Preferred Drug List (PDL): On July 1, 2003, TennCare will begin the implementation process of a single, statewide preferred drug list (PDL) that will replace the different drug formularies used by the TennCare managed care organizations (MCOs). The PDL will define the drug coverage for all TennCare enrollees. The PDL will be distributed to pharmacy providers and posted on the TennCare website (www.tennessee.gov/tenncare).

SECTION 2 PROVISION OF PHARMACEUTICAL SERVICES

Section 2.2: Compliance with Negative Drug Formulary, the TennCare PDL and TennCare Pharmacy Manual. In providing any pharmaceutical service to a TennCare enrollee, Pharmacy shall comply with the Negative Drug Formulary to the extent the Negative Drug Formulary applies to such Pharmaceutical Service, unless Pharmacy is otherwise directed by TennCare. Beginning on July 1, 2003, Pharmacy will comply with the TennCare PDL and assist the TennCare Bureau in gaining PDL compliance from prescribers. Pharmacy agrees further that it shall at all times comply with the TennCare Pharmacy Manual in providing Pharmaceutical Services to TennCare enrollees.

Section 2.7: Submission of Claims. Upon TennCare's request and as set forth in the TennCare Pharmacy Manual, Pharmacy shall submit all claims for Pharmaceutical Services provided under this Agreement via the TennCare POS on-line pharmacy claims processing system to TennCare for adjudication of such claims. All ambulatory pharmacy claims must be submitted via the online point-of-sale (POS) pharmacy claims processing system vendor contracted with the TennCare Bureau. Long term care pharmacy claims for eligible, TennCare/Medicare enrollees must be submitted via online or batch electronic claims media to the vendor contracted with the TennCare Bureau. Pharmacy claims may be submitted to TennCare up to three hundred sixty-five (365) days from the original date of service, unless otherwise approved by TennCare.

Section 2.9: 14-Day Supply. Authorization of drugs, including prior approvals of non-preferred drugs and medical necessity reviews of non-preferred drugs, or denial of authorization of drugs shall be rendered by TennCare or its subcontractor within twenty-four (24) hours of the formal request for authorization. Upon determination that a prescription is not covered under the approved formulary or PDL, or the prescription requires a prior authorization that was not obtained, the Pharmacy will immediately attempt to contact the prescriber to offer PDL or formulary alternatives or assist the prescriber in obtaining authorization. If the prescriber cannot be reached in a timely fashion, or the prescriber insists that there are no acceptable PDL or formulary alternatives, or TennCare (or its agent) does not render a decision on the day of request, the Pharmacy must provide a 14-day emergency supply of the prescribed medication, provided that:

- (a) The medication is not a drug category specifically excluded from the TennCare formulary:
 - Research drugs
 - Medical supplies and durable medical equipment
 - Injectables (except for in-home use administered by patient)
 - Cough and cold products (except those listed in the OTC formulary)
 - Biologicals
 - Blood and blood plasma
 - DESI, LTE, IRS drugs
 - Nutritional and dietary supplements
 - Most vitamins (see negative and OTC formularies)
 - Antiobesity products
 - Topical minoxidil
 - Anti-acne products
 - Diagnostic products
 - Cosmetic drugs
 - Smoking Cessation products
 - Fertility Drugs
- (b) The medication is not a drug in a non-covered TennCare therapeutic category (e.g., appetite suppressants, drugs to treat infertility); or
- (c) Use of the medication is not contraindicated because of the patient's medical condition or possible adverse drug interaction; or
- (d) If the patient is not already taking the medication, use of the medication for a fourteen day (14) period possibly followed by abrupt discontinuance of the drug would not be medically contraindicated; or
- (e) The prescriber did not prescribe a total quantity less than a fourteen (14) day supply, in which case the pharmacist must provide a supply up to the amount prescribed; or
- (f) Provision of the fourteen (14) day supply would not violate state or federal Controlled Substances Laws.

If the TennCare Bureau or its agent denies authorization of the drug requested and the prescriber insists there are no acceptable PDL or formulary alternatives or the enrollee wants the decision to be reconsidered, the Pharmacy and TennCare must provide the prescribed medication pending the conclusion of a grievance appeal to the Bureau of TennCare. A TennCare Drug Store Notice, explaining the patient's right to appeal must be given by the Pharmacy to the enrollee. The Pharmacy shall prominently display the notice of the fourteen-day (14) emergency supply policy at each service site. TennCare may, at its option, provide the language for the poster or will provide the posters, with personnel trained on the proper appeal procedures. Failure to provide a fourteen (14) day supply of the prescribed medication as described above or failure to post the notice may result in a material breach of the Participation Agreement and result in fines or termination of the agreement.

SECTION 3 PAYMENT FOR PHARMACEUTICAL SERVICES

Section 3.9: Non-covered therapeutic Drugs: Under the TennCare Program, Pharmacy will be reimbursed for covered services if such services are medically necessary and on the TennCare PDL; provided, however, that non-covered therapeutic classes, (e.g., Appetite suppressants, drugs to treat infertility), DESI, LTE and IRS drugs shall be explicitly excluded. For these purposes, (a) “DESI” means Drug Efficacy Study and Implementation whereby drugs may be found to be LTE or IRS, (b) “LTE” means less than effective as determined by the Food and Drug Administration and (c) “IRS” means identical, related or similar to DESI or LTE. A partial listing of these DESI, LTE and IRS drugs may be found on the TennCare website (www.tennessee.gov/tenncare).

Covered services under the Agreement shall include Early and Periodic Screening, Diagnosis and Treatment (“EPSDT”) services as medically necessary in accordance with 42 CFR Part 441 Subpart B and the Omnibus Budget Reconciliation Act of 1989 for children under the age of 21. Such screening shall be done in accordance with the periodicity schedule set forth in, and all components of this program shall be consistent with, the latest “American Academy of Pediatrics Recommendations for Preventative Pediatric Health Care.” Pharmacy shall make all treatment decisions under the Agreement with respect to children under the age of 21 based upon medical necessity in light of such child’s individual medical and behavioral health needs.

SECTION 6 LAWS, REGULATIONS, AND LICENSES

Section 6.4: Incorporation by Reference of Federal and State Law/Regulation: By reference, this agreement incorporates all applicable federal and state laws and regulations and any applicable court orders or consent decrees, and any and all revisions of such laws or regulations shall automatically be incorporated into the Participation Agreement as they become effective.

SECTION 9 TERM AND TERMINATION

Section 9.3: Termination by TennCare. This agreement may be terminated at any time by TennCare upon written notice to Pharmacy:

- (i) following written notice from TennCare that Pharmacy is in material breach of its obligations under this Agreement or any applicable agreement and the expiration, without cure of such material breach, of thirty (30) days after Pharmacy’s receipt of such notice; or,
- (ii) in the event Pharmacy willfully refuses to provide Pharmaceutical Services to a TennCare enrollee, except as provided in Section 4.2; or,
- (iii) in the event Pharmacy’s loss or suspension of licensure or loss of liability insurance required under this Agreement; or,
- (iv) following TennCare’s receipt from Pharmacy of an objection to a proposed amendment to this Agreement pursuant to Section 10.1(b); or,
- (v) the Pharmacy has been excluded from participation in the TennCare program by TennCare, a TennCare MCO, CMS, OIG or HHS; or,
- (vi) the Pharmacy has knowingly allowed a pharmacist who has been excluded from participation in the TennCare program by TennCare, a TennCare MCO, CMS, OIG or HHS to provide pharmaceutical services to TennCare enrollees; or,

- (vii) the Pharmacy has not complied with all of the emergency supply provisions contained in Section 2.9. above and any subsequent agreement amendments or revisions to court orders or consent decrees that pertain to the supply of emergency supply dispensings; or,
- (viii) the Pharmacy refuses to provide pharmacy services to a TennCare member solely because the member is unable to pay any or all pharmacy co-payments.

Section 9.5: Application of Pharmacy. It is the understanding of the parties that this Agreement shall be executed first by Pharmacy and upon such execution shall be an application by Pharmacy to become a party to this Agreement. As part of such application, Pharmacy shall complete the information in Exhibit A (Pharmacy Application). This signing of this Agreement by Pharmacy shall constitute an offer only, unless and until it is approved by TennCare in the State of Tennessee. This application by Pharmacy shall be accepted by TennCare only if Pharmacy meets all participation criteria established by TennCare and only at TennCare's sole discretion.

Section 9.6: Grier Revised Consent Decree Compliance. Section 2.9 of this Agreement requires Pharmacy to comply with the 14-day emergency supply provisions of the *Grier* Revised Consent Decree. If the Pharmacy is found to be in violation of the *Grier* Revised Consent Decree, the Pharmacy may be warned and given corrective training, fined or the Agreement terminated. Violations may include, but not be limited to, failure to dispense a 14-day emergency supply of a non-preferred drug when appropriate, failure to provide a TennCare Drugstore Notice (appeal and patient rights form) when appropriate and failure to post any TennCare-required notices in the pharmacy area regarding the *Grier* Revised Consent Decree. The first violation identified by TennCare will result in counseling and training regarding the violation and compliance with the *Grier* Revised Consent Decree by Pharmacy. Pharmacy will be required to submit to TennCare, within ten (10) days, a written corrective action plan that demonstrates, in detail, the steps taken by Pharmacy to assure the violation will not be repeated. A second violation of the pharmacy provisions of the *Grier* Revised Consent Decree by Pharmacy may result in the imposition of monetary penalties (fines) up to one thousand five hundred dollars (\$1,500) per violation. Violations of the *Grier* Revised Consent Decree will result in Pharmacy's forfeiture of any incentive payments associated to PDL compliance and referred to in Section 10.11 of this Agreement. Repeated violations by Pharmacy may result in termination of the Agreement.

SECTION 10 MISCELLANEOUS

Section 10.11: Participating Pharmacy Provider Incentive Payments: On or after July 1, 2003, TennCare will implement a single, statewide preferred drug list (PDL) that will define the pharmacy benefit for all TennCare members. Participating pharmacy providers will submit all TennCare pharmacy claims to the TennCare PBM for adjudication. Participating pharmacy providers are required to contact the prescriber in the event a TennCare member presents a prescription for a non-preferred or non-covered drug and request or suggest a covered alternative medication to replace the original (non-covered) prescription. After implementation of the first three phases of the PDL, TennCare will review pharmacy claims data every six months to analyze every participating pharmacy provider's compliance with the PDL. In the event a participating pharmacy provider maintains a ninety percent or greater PDL compliance rate for that six month time period, the participating pharmacy provider will be paid ten cents (\$0.10) for every TennCare prescription that participating pharmacy provider dispensed during that six-month time period. If any participating pharmacy provider is found to have violated the *Grier* Revised Consent Decree during that six-month time period, however, that participating pharmacy provider will forfeit all incentive payments for the period and be subject to the sanctions described in Section 9.6 above.

Section 10.12: Debarment and Suspension.

To the best of its knowledge and belief, the Pharmacy certifies by its signature to this Agreement that the Pharmacy and its principals:

- (a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal or State department or Pharmacy;

- (b) have not within a three (3) year period preceding this Agreement been convicted of, or had a civil judgment rendered against them from commission of fraud, or a criminal offence in connection with obtaining, attempting to obtain, or performing a public (federal, State, or Local) transaction or grant under a public transaction; violation of federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification, or destruction of records, making false statements, or receiving stolen property;
- (c) are not presently indicted for or otherwise criminally or civilly charged by a government entity (federal, State, or Local) with commission of any of the offenses detailed in section b. of this certification; and
- (d) have not within a three (3) year period preceding this Agreement had one or more public transactions (federal, State, or Local) terminated for cause or default.

The Pharmacy's signature on the Agreement shall serve as certification of compliance with this policy. If any doubt exists, officials may check a list maintained by the General Services Administration which lists persons who have been debarred, suspended or proposed for debarment under 45 CFR Part 76 or 48 CFR Part 9, Subpart 9.4. The list can be found at: <http://epls.arnet.gov/>

If a person is debarred, suspended or proposed for debarment during the term of the Agreement or if the State determines that an agency has misrepresented its status, a decision as to the type of termination action, if any, will be made after a thorough review to ensure the propriety of the proposed action. In this event, the Agreement will not be renewed or extended (other than no-cost time extensions).